

REMARKS

Following entry of the present Response and Amendment, claims 1-11, and 13-32 remain pending in this application, with claim 1 being the only independent claim.

The Office Action dated August 4, 2009 (the "Office Action") rejected all claims based under 35 U.S.C. § 103 as allegedly being rendered obvious by various combinations of the following references, among others: U.S. Patent Application Pub. No. 2003/0087877 (henceforth, "'877 Publication"), a 1995 article "Water-soluble ..." by Klein, U.S. Patent Application Pub. No. 2002/0037874 (henceforth, "'874 Publication"), and U.S. Patent No. 6,335,029 (henceforth, "'029 Patent").

In the present Response and Amendment, independent claim 1 has been amended herein to include the features of original claim 12, claim 12 has been cancelled, and various dependent claims have been amended to correct dependency and typographical errors. Claims 33-41, previously withdrawn, have also been cancelled. New dependent claim 42 has been introduced for examination upon the merits. Claims 1-11, 13-32, and 42 thus remain pending in the application.

Applicant respectfully requests reconsideration of the merits of the present application in accordance with these amendments and the following remarks.

35 U.S.C. § 103 Rejections

Independent claim 1 as presently amended has the same claim scope as previously presented claim 12. The Office Action based its obviousness rejection of the subject matter of claim 12 upon a combination of the '877 Publication, in view of Klein, the '874 Publication, and the '029 Patent. Insofar as this rejection applies to the claims as presently amended, Applicant respectfully traverses as follows.

The Office Action first alleges that the '877 Publication and Klein can be read together as teaching on skilled in the art use cold plasma deposition of a polymer containing amino groups to bind a biological molecule, such as heparin, in a "single step" as recited in claim 1 (Office Action at pg. 5). In making this conclusion, the Office Action completely disregards the teachings of the '877 Publication that the polymer must be surface treated with a Traut's reagent after the cold plasma deposition, and then application of an activating agent. The '877 Publication, in short, does not have "active functional groups capable of chemically

binding biological molecules.” These extra steps, taught as being necessary by the ‘877 Publication, are necessary because the ‘877 Publication in fact does not deposit by cold plasma a polymer having active functional groups capable of chemically binding biological molecules. These extra steps in the ‘877 Publication, necessary to create active functional groups after the deposition of the polymer, are exactly what the present invention avoids. See, e.g., applicant’s specification at pars. 9-13.

In relying upon Klein, the Office Action appears to argue that one skilled in the art would be motivated to deposit a polymer having active functional groups capable of chemically binding biological molecules onto a medical device by cold plasma because Klein allegedly teaches the reaction of heparin with a poly(acrylamide-allylamine) derivative. Even if Klein teaches as alleged, this still does not provide one skilled in the art with the motivation to produce applicant’s claimed invention. Nothing in Klein would suggest to skilled in the art to modify the process of the ‘877 Publication. It does not relate in any way to cold plasma deposition of polymers, or creating drug eluting stents, or even to creating biocompatible medical implants. The only rationale supplied for making the leap to apply these alleged teachings of Klein to the ‘877 Publication is that one skilled in the art allegedly “would have been motivated to directly react the biological molecule containing carboxyl groups without the use of Traut’s reagent because it would require less steps to produce the biological material.” See Office Action at pg. 5.

Not only is this conclusion merely impermissible hindsight, but it ignores the realities of combining these two references. Namely, one skilled in the art would not have been able to predict the behavior of a plasma-deposited allylamine polymer of the ‘877 Publication according if reacted in the same manner as the polyacrylamide of Klein. First, the polyacrylamide has amide groups, whereas the allylamine plasma deposited conserves amino groups, which do react very differently. Second, the polyacrylamide is very hydrophilic and tends to hydrate, while plasma deposited allylamine is hydrophobic, as also disclosed in the present application. See, application at par. 20. In fact, the fact that the plasma deposited polymer is hydrophobic makes it particularly suitable as a means for treating drug eluting stents, as it prevents the stent from losing the drug during subsequent treatment to add the biocompatible anti-thrombogenic outer layer.

Thus, polyacrylamide could not have been taken as a close equivalent of the plasma

deposited allylamine and one skilled in the art would not be motivated to make the leap of logic posited by the Office Action.

The '874 Publication likewise fails to remedy these deficiencies of the '877 Publication. The '874 Publication teaches only sulphated derivatives of hyaluronic acid that can be useful for their anti-thrombogenic properties. Again, nothing in that reference would lead one skilled in the art to deposit by cold plasma a polymer having active functional groups capable of chemically binding biological molecules.

Claim 1 as presently amended further distinguishes over the prior art because it recites that the polymer having active functional groups capable of chemically binding biological molecules is applied to the medical device after applying first to the device at least one layer of a drug incorporated in a material capable of eluting said drug. In rejecting previously present claim 12, the Office Action alleges that the '029 Patent teaches one skilled in the art to modify the '877 Patent in this manner. In making this rejection, the Office Action is not properly reading the '029 Patent and applicant's claim.

Specifically, the '029 Patent US '029, discloses a device comprising at least one layer (5) comprised of at least one bioactive agent in a polymeric matrix, and at least one barrier (20) positioned over the layer comprised of at least one bioactive agent. The barrier layer (20) is formed in situ by a low energy plasma polymerization process of a monomer gas or by a vapour deposition process. This barrier (20) is taught as being for the purpose of controlling the release of the bioactive agent. *See, e.g.*, '029 Patent at column 7, lines 33-34. This reference therefore only teaches an outer barrier layer that does not contain any active functional groups for chemically binding bioactive compounds being deposited over a layer containing a bioactive agent. While the '029 discloses that its device may be dipped or sprayed in heparin, this does not mean (1) that the barrier layer has any type of functional groups for chemically binding the heparin, or (2) that one skilled in the art would conclude that this technology in any way could be used to modify the '877 Publication in a manner to produce the invention of claim 1. As such, claim 1 is further distinguishable from the prior art of record for these reasons.

The various other prior art references cited in the Office Action against various other dependent claims do not contain any of the features described above as distinguishing claim 1 from the prior art. As such, since claim 1 is the sole independent claim pending in this

application, all claims are allowable over the prior art of record for the reasons set forth herein.

New 42

Applicant has hereinto introduced new dependent claim 42 for examination upon the merits. This claim is allowable for all of the reasons previously made of record for independent claim 1.

Favorable consideration of the above remarks and claims, and a timely Notice of Allowance is thus respectfully requested.

Conclusion

In view of the foregoing, the Applicant respectfully requests that the Examiner enter the above-noted amendments, and that the above remarks be fully considered in conjunction reconsidering the present claims. Timely allowance of all pending claims and the issuance of a Notice of Allowance are requested.

While none are believed to be necessary at this time, if additional claims fees are believed due at this time in connection with this Response and Amendment, or if the appropriate fees have not been paid for the one-month extension of time requested herewith, please charge the fees to our Deposit Account No. 50-1349. Also, please credit any previous overpayments to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicant's undersigned representative via telephone to discuss the present Response and Amendment if any issues are found in the present claims. Applicant believes such a telephone call would likely progress prosecution of this application toward allowance more quickly than would mailing of a further Office Action.

Respectfully submitted,

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